510(k) Summary
NordicImagingLab AS
nordicBrainEx Software

AUG 2 5 2009

Submitter: NordicImagingLab AS
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Primary Contact: Chandana Gurung Bhandari (Chandana@nordicimaginglab.com)

Proprietary Name:	nordicBrainEx Software
Device Common Name:	PACS
Device:	System, image processing, radiological
Classification Name:	Picture archiving and communication system
Classification Regulation:	892.2050
Class:	II
Panel:	Radiology
Product Code:	LLZ

Predicate device name: Nordic Image Control and Evaluation (nordicICE) Software, K090546

Device Description

The nordicBrainEx Software is a post-processing application for functional MRI data developed with a view to ease of use and high performance on a standard Windows workstation. The software provides comprehensive functionality for processing and analyzing BOLD fMRI and DTI data, in addition to efficient and easy to use tools for visualization and report generation. The application workflow has been optimized to ensure efficiency and high throughput in a clinical environment.

Intended Use

nordicBrainEx is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

nordicBrainEx provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including blood oxygen level dependent (BOLD) fMRI, diffusion weighted MRI (DWI) / fiber tracking and dynamic analysis.

BOLD fMRI: BOLD analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood-flow resulting from neuronal activity.

DWI/Fiber Tracking: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilize the directional dependency of the diffusion to display the white matter structure in the brain.

Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary.

Technological Characteristics and Substantial Equivalence

The nordicBrainEx Software is substantially equivalent to the nordicICE Software (K090546) in intended use, indications for use, technological characteristics and operational characteristics.

Performance Testing

Prospectively defined verification and validation activities for the nordicBrainEx Software assure that the nordicBrainEx Software is substantially equivalent to the cleared nordicICE Software and meets design and performance specifications as well as user needs when operated according to the operating instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Chandana G. Bhandari
Quality Manager
NordicImagingLab AS
Møllendalsveien 65C
Bergen
Norway, 5009

AUG 2 5 2009

Re: K092102
Trade/Device Name: nordicBrainEx Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 10, 2009
Received: July 14, 2009

Dear Ms. Bhandari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092102

Device Name: nordicBrainEx Software

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092102